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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/322,732 05/28/99 MAROTTI

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WOODCOCK WASHBURN KURTZ MACKIEWICZ & NOR
ATTENTION: SUZANNE E. MILLER ESQ.
ONE LIBERTY PLACE, 46TH FLOOR
PHILADELPHIA PA 19103

EXAMINER

ROBINSON, H

ART UNIT

PAPER NUMBER

1653

14

DATE MAILED:

06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/322,732

Applicant(s)

Marotti et al.

Examiner

Hope Robinson

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1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 15-18, 140, and 141 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 15-18, 140, and 141 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

1. Applicant's response to the Office Action mailed January 19, 2001 in Paper No. 12 on April 23, 2001 is acknowledged.
2. Claims 9-14 and 19-139 have been canceled. Claims 6 and 15 have been amended. Claims 1-8, 15-18, 140 and 141 are pending.
3. The following grounds of rejection are or remain applicable :

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8, 15-18 and 140-141 are rejected under 35 U.S.C. 112 first paragraph, because the specification is not enabled for the full scope of the claims. The claimed invention is directed to new methods or procedures to screen for, detect and/or characterize new compounds that modulate the function of efp in prokaryotic cells. These methods or procedures include new in

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vitro methods as well as new in vivo methods (see page 4). However, the specification provides only examples and no specific assays to accompany the claimed method. Furthermore there is no indicia of how the claimed method is an improvement over the prior art. See for example on page 14 where the specification states that cell-free extract is an example of an assay that can be performed. In addition, the specification asserts that contacting can take place in buffers or media well known to those skilled in the art. Further, varying amounts of the test compound can be used as desired by the practitioner. Therefore, it appears that the new method encompasses a lot of old methods and that much of the parameters involved in the method can be adjusted arbitrarily.

Additionally, the specification asserts that the claimed method will identify a compound that modulates the activity of prokaryotic efp, determine whether the compound modifies activity of efp, for example determining if the compound binds to efp by a number of art-recognized procedures (i.e. binding assays such as gel-shift mobility electrophoresis, Western blot, filter binding and scintillation proximity assay). Note that the claimed method is relying on art-recognized procedures, yet the specification asserts that this is a new method/procedure. Furthermore, the information provided in the specification is exemplary and not limiting, therefore, does not breathe life into the claims. In view of the foregoing, one skilled in the art would have to engage in undue experimentation to be able to practice the full scope of the claims since the specification does not provide sufficient detail.

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In the absence of sufficient guidance/direction regarding the steps to determine whether the test compound modulates the activity of efp one skilled in the art would not be able to practice the claimed invention commensurate in scope with the claims. In addition, the claims broadly recite a method of identifying a compound that modulates the activity of efp, however, there is no specific assay and measurements to obtain this information nor information as to whether modulation is up or down (see for example claim 1). Note for example that the prior art teaches that genes encoding certain ribosomal proteins can be deleted from the chromosome without an apparent effect on cell viability. It is also stated that most initiation, elongation and termination factors are required for cellular growth, however, some of these proteins may be dispensable under certain growth conditions (Aoki et al., The Journal of Biological Chemistry, vol. 272, no. 51, 1997). In view of the prior art the specification needs to provide guidance as to how the compound is determined, what the compound is, what efp activity will be modulated, what effect the modulation will have on the function of the efp and a specific assay and measurement steps to achieve all of the above. Further, claim 2 recites "binding" and claims 140-141 recites "an association" which again does not describe the claimed activity of efp that is modulated or how the essential protein(s) are modified.

Absent exemplification of a specific assay to assay a specific compound and a description of the activity being affected, the specification is not enabled for a method that modulates the activity of efp. Further, since no guidance or direction is provided regarding the determination of

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the test compound it would require undue experimentation to be able to practice the claimed invention.

Thus, for all of the above reasons, the specification is not considered to be enabling without undue experimentation, because, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable one skilled in the art to be able to practice the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8 and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and the dependent claims hereto remain indefinite because claim 1 recites a method that modulates the activity of prokaryotic elongation factor p. However, the claim does not recite whether modulation will be upward or downward. The claim is further indefinite because the claim recites "determining whether said compound modifies activity of ef_p" and there is no indication of how, no measurement steps are included in the method (see also the dependent claims). Note also that the compound to be identified is not named or described.

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Claim 6 as amended is indefinite because the claim recites “(c) ... which modulates the activity of efp modifies the activity of other protein(s)”. Note that the claim does not recite what activity of the efp is being modulated or how the activity is modified for other protein(s) essential for the functioning of efp. Furthermore, the “other protein(s)” are not described or named. The dependent claims are also included in this rejection.

6. Applicant’s arguments filed April 23, 2001 in Paper No. 12 have been considered.

Regarding the rejections under 35 U.S.C. 112, first paragraph the rejection remains because applicant’s arguments were not persuasive. Applicant argues that “the only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of 112 requires nothing more than objective enablement”. As the specification is not enabled for the full scope of the claims for the reasons indicated above, does not provide sufficient guidance/direction to practice the claimed method or examples that demonstrate the claimed method commensurate in scope with the claims, more than an “objective enablement” is required. Applicant’s response on page 5 argues that the “present invention is directed in part, to new and useful methods of screening compounds that modulate efp and efp-associated cell functions. Furthermore, the methods include, for example, in vitro cell based and cell free extract assays to determine the affect of the compound on cell function. Compounds affecting such cell functions have the potential to mediate cell viability and, thus, are candidates for use in treating microbial infections in mammals and as disinfectants”. However, the specification does not

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demonstrate this. Applicant also argues that “examples 1-5 may be employed to practice the claimed method. One of ordinary skill will recognize that the claims do not depend upon any particular underlying assay employed. To this end, the assay may vary, and may even include, and indeed do include, assays not set forth in the specification. In addition, the assay employed may be modified as the practitioner in the art sees fit”. This argument is not persuasive because if the specification is devoid of assays that are needed to practice the claimed invention or if the assays can be modified as one skilled in the art sees fit because the claimed invention does not have a specific assay for the claimed invention, then the claimed method is not reproducible and one skilled in the art would not be able to practice the claimed invention without undue experimentation. See for example, Example 1, which describes an assay to identify compounds that bind to efp by displacing a bound oxazolidinone, however, identifying compounds that bind efp does not equate to compounds that modulate efp activity. As compounds could bind and have no effect on the function of efp, the specific activity of efp that is modulated is not described and there is no indication of the effect of the compound once bound to efp in this example. Thus, the specification is not enabled for the full scope of the claims.

It is noted that applicant cited *In re Mercier*, however applicant’s argument and the citation of *In re Mercier*, were not sufficient to obviate the rejection under 35 U.S.C. 112, second paragraph. Note that the claimed method (see for example claim 1) has no clear detection step or a step that clearly delineates how the method will determine whether the compound modifies

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activity of efp. The dependent claim 2 recites that the method will determine if said compound binds to efp, however, binding of efp does not define the activity that is claimed in step (b) of claim 1. Thus the claimed method remains incomplete. Applicant's arguments on page 2 of the response state that "modulation can be either an increase or decrease and refers to page 10 of the specification. However, the claims are only read in light of the specification, thus, the limitations of the specification cannot be read into the claims. The response also argues that "applicant's claims are not indefinite simply because they are not limited to an increase or decrease". Note that other issues were raised in the rejection of claim 1 for the reasons set forth above. Thus, the claimed method recited in claim 1 needs to set forth complete and clear method steps to be definite.

In regard to claim 6 applicant argues that the language "other protein(s) essential for the functioning of efp", is definite because examples of such proteins are provided in the specification. However, as indicated above the limitations of the specification cannot be read into the claims, thus this argument is not persuasive. Applicant also point to the "L16 protein" which is not recited in claim 6. It is suggested that applicant rewrite claim 6 to recite the limitations of claim 7.

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Conclusion

7. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. No claims are presently allowable.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 6:00 pm (EST).

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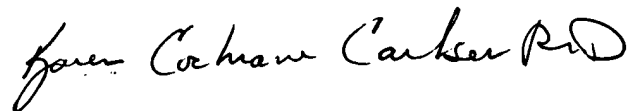
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER